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BEFORE THE COMMITTEE ON GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES

Oversight Hearing Concerning the Implementation of Project Bioshield

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Mr. Chairman, Congressman Waxman, distinguished members of the Committee:

Thank you for the opportunity to testify before you today. Before I begin, allow me to thank you personally for your longstanding leadership, both as a Committee and individually, to help safeguard this nation against terrorism, and specifically against the threat posed by weapons of mass destruction. Your Committee has been at the forefront of working to ensure that our federal homeland security programs and policies have been as effective and efficient as possible, including in the area of countering nuclear, biological and chemical terrorist threats.

My name is Richard Hollis. I am Chairman and Chief Executive Officer of Hollis-Eden Pharmaceuticals. Hollis-Eden is a San Diego-based biotechnology company, publicly traded on the NASDAQ stock exchange. Hollis-Eden has under development a number of proprietary immune-regulating hormones, compounds that are key components of the human immune system. We believe that by properly utilizing these hormones, we can help the body to mount an appropriate immune or metabolic response to a host of different diseases or immune system challenges. Specifically, we have developed and tested our compounds for the potential treatment of Acute Radiation Syndrome (ARS), HIV/AIDS, tuberculosis, malaria, cystic fibrosis, rheumatoid arthritis, and multiple sclerosis, among other possible applications.

THE NUCLEAR THREAT

Mr. Chairman, virtually every day brings news of the growing threat posed by nuclear proliferation and by the ongoing efforts of Al Qaeda and other terrorist groups to obtain nuclear weapons. We have seen with the attacks last week in London that the enemy will continue to strike us. Thankfully, they used conventional explosives. But the next time, they might not. We simply cannot afford to take that risk—we must be prepared.

In light of this threat, national security experts routinely cite the threat of nuclear attack by a rogue state like North Korea or Iran or by a terrorist group as the number one security threat facing this country. During the 2004 Presidential Debates, both President Bush and Senator Kerry agreed that the single greatest threat to our nation was a nuclear weapon in the hands of a terrorist. A few weeks ago Governor Tom Kean and your

former colleague Lee Hamilton, the leaders of the 9-11 Commission, appeared on "Meet the Press" along with former Senators Sam Nunn, Fred Thompson, and Senate Foreign Relations Chairman Richard Lugar to discuss the threat of nuclear terrorism. At the end of the program, host Tim Russert asked each guest, given all they know about subject of nuclear terrorism, in their best judgment did they think that within their lifetimes they would witness a nuclear bomb going off in an American city? Unfortunately each guest replied in the affirmative.

Governor Kean then elaborated: "Not only do I believe America will experience a nuclear bomb in my lifetime but everyone I have spoken to that is an expert on the subject believes so too." The program also quoted CIA Director Porter Goss when he stated, "It is "only a matter of time before al Qaeda tries to use a chemical, biological or nuclear weapon against the United States."

Most recently, the head of the Domestic Nuclear Detection Office at the Department of Homeland Security, Vayl Oxford, stated that, "A lot of people want to quibble about the nature of the nuclear threat. I tell my people, assume there is a 100 percent chance someone will try to attack us with a nuclear weapon in the next five to 10 years." Similar conclusions have been reached by a number of recent prominent analyses of the threat of a nuclear or radiological attack, including those by Harvard professor Graham Alison, the Monterrey Institute, and the Nuclear Threat Initiative, headed by former Senator Sam Nunn.

These fears are well founded:

- In May 1998, Osama bin Laden issued a statement entitled "The Nuclear Bomb of Islam," proclaiming that Muslims have a duty to acquire nuclear weapons and terrorize the enemies of God, in particular the United States. In an interview with Rahimullah Yousafsai from *ABC News* he stated, "acquiring [nuclear] weapons for the defense of Muslims is a religious duty."
- During the trial of Osama bin Laden for the 1998 US Embassy bombings, prosecution witness Jamal Ahmad al-Fadl detailed his efforts to assist Bin Laden in an attempt to acquire uranium, presumably for the development of nuclear weapons from a source in Khartoum, Sudan, in late 1993 or early 1994.
- The Arabic newspaper *Al-Hayat* reported in late 1998 that bin Laden had made a $30 million deal in Chechnya to purchase twenty nuclear warheads stolen in Russia by Chechen rebels. Bin Laden reportedly gave the contacts in Chechnya $30 million in cash and two tons of opium in exchange for approximately 20 nuclear warheads. Sources stated that bin Laden planned to have the warheads dismantled by his own team of scientists, who would then transform the weapons into "instant nukes" or "suitcase nukes."
- In September 1998, bin Laden's aide, Mamdough Mahmud Salim, was arrested in Munich, Germany on charges of attempting to obtain highly enriched uranium (HEU) in the mid-1990s.
- Director George Tenet told Congress in January 2002 that the United States uncovered rudimentary diagrams of nuclear weapons in a suspected al Qaeda

house in Kabul. According to a CIA report released publicly on January 30, 2002, these "diagrams, while crude, describe the essential components, uranium and high explosives, common to nuclear weapons."

- In November 2001, CNN reported that an Arabic document titled "Superbomb" was found in the home of Abu Khabbab, the codename of a senior al Qaeda official. The document discussed various types of nuclear weapons, the physics of nuclear explosions, the materials needed to make them, and their effects on urban centers.
- Two Pakistani nuclear scientists, Sultan Bashiruddin Mahmood and Chaudiri Abdul Majeed, admitted that they had had long discussions with al Qaeda operatives in August 2001 about the development of nuclear weapons. Pakistani officials told *The Washington Post* that the scientists reportedly admitted meeting with bin Laden, Egyptian Ayman Zawahiri, and two other al Qaeda officials to discuss the procurement of nuclear weapons materials and technology.

LACK OF PREPARATION TO ADDRESS THE NUCLEAR THREAT

The results of a nuclear attack on this nation would be devastating. The Department of Homeland Security's nuclear National Planning Scenario (NNPS) estimates that the number of dead from a terrorist attack on a major U.S. city would be in the hundreds of thousands, possibly reaching one million. Potentially millions more people would become seriously ill.

The reality is that, as of today, the vast majority of these deaths are preventable—assuming we act to prepare the nation to respond to such an attack.

Contrary to popular belief, the majority of the victims of a nuclear attack would die not from the blast but from Acute Radiation Syndrome (ARS). ARS is the result of radiation-induced bone marrow damage. Specifically, ARS is characterized by the loss of infection fighting cells and clotting elements that are produced in bone marrow. This loss of the body's ability to fight infection and prevent bleeding is believed to be the leading cause of sickness and death in the event of a nuclear attack. In fact, some estimates of the medical consequences from a nuclear bomb indicate that ARS would likely kill three to five times as many people as the initial blast.

The British Medical Journal recently estimated that a 12.5 kiloton bomb detonated in New York City would kill at least 50,000 people instantly. But another 200,000 would be expected to die later from ARS and an estimated 700,000 more would become sick from the affects of ARS. The report also states that in a disaster of this magnitude, hospitals and other health care providers would be immediately overwhelmed, leaving the vast majority of victims with few or no treatment options.

There are simply not enough hospital beds to address such a surge. This situation would be compounded by the fact that perhaps millions of "worried well," those who only believe they may have been exposed to radiation, would seek treatment at the same time as those who really do need treatment.

To date, our nation has no workable plan to address the needs of these potentially millions of sick and worried well in the aftermath of a nuclear attack. The key to such a plan is the ability to treat ARS.

If you can manage ARS you can send in first responders. If you cannot, victims will be on their own. If you can manage ARS you can evacuate people in an orderly fashion while radiation levels are subsiding. If you cannot, mass evacuation becomes virtually impossible. If you can treat ARS you can save victims' lives. If you cannot, the nation will have little to offer to victims. In short, if you can effectively treat ARS after a nuclear attack you can save hundreds of thousands of American lives.

Sixty years after the atomic blasts at Nagasaki and Hiroshima, there remains no drug licensed or deployed to treat ARS. The only drugs now available for radiation injury are Potassium Iodide, which helps to prevent thyroid cancer years from the time of exposure, and "chelating" agents like Prussian Blue, which may help rid the body of certain types of radioactive isotopes from fallout, but which do nothing to address initial bone marrow injury, the main cause of ARS.

Senator Robert Byrd (D-WV) specifically asked HHS, in connection with a recent Senate hearing on Project Bioshield, about the status of developing and acquiring effective medical countermeasures to ARS. In response, Assistant Secretary Stewart Simonson stated that HHS had acquired potassium iodide and had the ability to use other, extremely expensive drugs, presently used to treat cancer patients, under an emergency use IND for an off-label indication.

This response ignores the fact that potassium iodide is <u>not</u> a treatment of ARS, but again only helps mitigate the long-term risk of thyroid cancer. Moreover, this response ignores entirely that the cancer treatments referred to in Mr. Simonson's response are not only expensive and have to be refrigerated but also they must be administered by a doctor under highly controlled circumstances with adjunctive therapies such as antibiotics and platelets in a hospital. As stated above, there is no scenario where any one city would have adequate hospital beds to address the surge capacity following detonation of a nuclear device on U.S. soil.

Thankfully, there is an alternative.

THE ANSWER: NEUMUNE, THE WORLD'S FIRST NUCLEAR MEDICALCOUNTERMEASURE

Mr. Chairman, the good news I am here today to deliver to you and the American people is that such a drug is not only possible, but it is at hand. My company, Hollis-Eden is actually on the verge of delivering what we believe will be a monumental medical and historical breakthrough: a drug that can dramatically improve Americans chances for survival in the event of a nuclear attack.

Two weeks after the devastating September 11, 2001 attacks on our country, officials from the Armed Forces Radiobiology Research Institute ("AFRRI"), a research division of the Department of Defense, approached Hollis-Eden and informed us that they wanted to fast track the development of one of our experimental drugs for the treatment of ARS. In some early studies with mice, AFRRI found that our compound coded HE2100 or Neumeune saved literally 100 percent of the lab animals that would have otherwise died from acute radiation exposure. Since that time, AFRRI has continued testing and publishing results in the medical literature on this compound for use in mitigating the effects of ARS.

To date, results of test in over 200 non-human primates treated with NEUMUNE demonstrated the drug to be safe and effective in the treatment of ARS. In one recent trial, 90 percent of the treated primates survived otherwise lethal doses of radiation, while only 55 percent of the untreated group survived. Extrapolating these results using the numbers of people who will be exposed to ARS in a nuclear attack on a major American city shows the dramatic effect this drug could have in reducing the number of casualties in such an event.

Testing to date has shown that the drug is stable at room temperature and can be easily stockpiled. It can be self-administered in the field by victims of such an attack without the need for clinical support, thereby freeing-up medical resources that would otherwise be stretched beyond the breaking point. Moreover, the drug has exhibited no significant side effects. And assuming a contract of sufficient size to offer economies of scale, we believe can provide the drug at a cost akin to that of a standard antibiotic—approximately $75 to $100 per dose regimen.

IMPLEMENTATION OF BIOSHIELD HAS FAILED TO ADEQUATELY ADDRESS THIS THREAT

After a three-and-a-half-year long relationship with the federal government to get such a drug procured and into our civilian and military drug procurement, we have begun to see initial signs that the government is prepared to move forward with procurement of a treatment for ARS.

On May 20 of this year, the Department of Health and Human Services issued a Special Notice, advising of its intent to issue a draft Request for Proposals by the end of this month to acquire a drug for the prevention and/or treatment of Acute Radiation Syndrome. This follows the Department's issuance of a Request for Information notice on October 19th, 2004, which we were happy to respond to. While this is certainly positive, it appears that HHS intends to pursue an extremely conservative approach to procure an ARS therapy and is not utilizing the expedited authorities Congress provided under Project Bioshield.

That said, HHS is well aware based upon the results of the RFI response and market surveys, that there is simply is no other single product that can match the lifesaving abilities of Hollis-Eden's NEUMUNE for the treatment of ARS. Thus, HHS should make use of the authorities under Project Bioshield, or even the typical-FAR authorities, to award a contract to Hollis-Eden as quickly as possible. While there are other products that purport to treat ARS, they are in very early stage of development, only beginning the regulatory process for licensure. Moreover, they are being produced by more or less "virtual" companies that have spent less than $300,000 in the development of their purported treatments based upon public filings. Thus, the very idea that HHS will conduct a competition for a product it knows has no comparable equivalent simply does not make sense.

For this reason, earlier this week, Hollis-Eden has prepared and submitted an unsolicited proposal under Part 15.7 of the Federal Acquisition Regulations to allow HHS to immediately procure NEUMUNE for the SNS. This proposal meets each and every legal requirement for acceptance under existing law and regulation. By promptly evaluating this proposal, and awarding a contract to Hollis-Eden for procurement of adequate supplies of NEUMNE under existing authorities, HHS can assure the nation it is prepared for the scenario that leaders such as Governor Kean and Congressman Hamilton have said is all but inevitable.

We heartily welcome HHS' recent movements to finally address ARS, and look forward to continuing to partner with the federal government to provide the country with safe and effective medical countermeasures to radiation exposure by the prompt review and positive response to our Unsolicited Proposal.

THE FUTURE OF THE BIOSHIELD PROGRAM

With the background of my companys' experience with ARS, I would like to offer a few observations about the implementation of Bioshield and the future of the emerging biological, chemical, and nuclear defense industry.

Many in both the pharmaceutical and national security circles look to Hollis-Eden as a model for the BioShield Program:

- We are, we believe, the first truly new, post 9-11 medical countermeasure to a WMD threat.
- As Bioshield envisions, we have developed this drug almost exclusively with private investment capital and not taxpayer dollars. We have spent and continue to spend tens of millions of dollars to fund expensive trials and other development costs conducted by AFRRI and elsewhere. In fact, we have spent over $100 million to develop NEUMUNE, and we are on the verge of spending millions more for the required pivotal efficacy and safety trials for the drug to qualify for approval, which we believe could be during the first half of 2006.

We have done all of this with no guaranteed market for the product, government or otherwise. Rather, we have developed this drug under the belief and understanding that the federal government would enter into an advanced purchase contract to procure a safe, practical and cost effective drug with the potential to save hundreds of thousands of American lives if a nuclear terrorist incident were to occur in one or more of our cities.

We believe that when Congress passed Project Bioshield it did so with the intent of stimulating the private sector biotechnology and pharmaceutical industries to develop the next-generation of medical countermeasures to WMD.

The bill as described by Dr. Mark McClellan at the 2003 BIO CEO conference was very straightforward and initially very attractive to companies and investors. He described the process as one in which the secretaries of HHS and DHS would collaborate and agree on the major chemical, biological, radiological and nuclear (CBRN) threats and unmet medical needs to those threats. Once the threats were established, HHS would then assess what type of medical countermeasures were needed to address that threat. During the scientific assessment of new technology if the scientific experts thought it was feasible to develop such a countermeasure within eight years, the federal government would enter into an advanced purchase contract with that company committing the federal government to buy the product upon successful FDA approval. Dr. McClellan went on to emphasize that Bioshield advance purchase contracts must be of a size and scope—"hundreds of millions of dollars"—that would be sufficient to encourage private industry to participate and to justify their fairly risky investment in biodefense product development.

It is my view that Congress did not intend Bioshield to be just another pot of money from which to procure existing drugs, or to only award contracts for new vaccines and therapies to companies and products that have been funded entirely from NIH grants. Unfortunately, it is our view that this is, to a large degree, how the system has played out in the agencies. This has profound ramifications for the future of the Bioshield Program.

However, there is another way: direct that HHS and other relevant agencies to simply implement the law as written.. The federal government would be well served by simply making better use of the authorities the President proposed and Congress has provided and the President proposed in Project BioShield rather than the business-as-usual approach we have seen on ARS countermeasures.

In order for the federal government to more effectively implement the authority and funding it has been granted under Project Bioshield, I would make five main recommendations:

1. Defining markets: In the Bioshield statutory model the government must early on define the market: We will contract for X doses of a drug to respond to Y threat payable upon delivery of an approved product. This is critical because unless the private sector has a clear sense abut what the federal government needs—and what it is willing to buy—the private sector will not invest in the mere hope that the government may one day

procure a certain countermeasure. Absent a defined market, pharmaceutical companies will focus their resources and money in finding new cures for premature baldness, heart disease and erectile dysfunction—drugs they know consumers will buy. In order to harness the ingenuity and resources of the pharmaceutical industry the market needs to be defined and this market needs to provide an adequate return on investment to justify the opportunity costs.

2. Risk and funding: A second key question for the future of Bioshield is who should bear the risk of the drug development process. BioShield was designed to provide early market signals to encourage the private sector to invest in—and bear the risks of—developing new drugs for WMD threats. However, Bioshield has increasingly appeared to be reverting back to a more traditional government-funded research and development program, one in which HHS selects specific grant recipients to fund experimental development efforts.

The risk of this government grant model is two fold. First, only one in ten drug candidates ever receive FDA approval and make it to market. If HHS utilizes Project BioShield to focus on drug development and not procurement, as might appear to be the case thus far, the odds are against picking drugs that will ultimately make it into the Strategic National Stockpile. Second, if HHS picks winners and losers at the early development stage, the industry as a whole will not expend its potentially vast sums of private R&D capital to develop these products for the federal government. Instead, this will become a niche market made up of just a few NIH/HHS companies dependent on federal research grants. As a result, the breadth of technology, knowledge and discovery that will be focused on safeguarding this nation will be only a fraction of what a broader, private sector-based program would provide.

3. Timing and speed: In its May 2005 edition, *Forbes* published an article about the procurement decision to buy a next-generation vaccine for Anthrax. In that article, a former senior-level HHS official from was quoted as saying; “Bioshield was always designed to bring in new products, it was not a piggy bank to buy licensed products.” I believe our lawmakers intended Project Bioshield to dramatically speed the development and procurement of new products, by utilizing the law to enter into contracts to procure drugs at an early stage of development. Language from the bill states “potential contractors have to show necessary measures of minimum safety and effectiveness; estimated price for each dose or effective course of treatment regardless of dosage form; and other information that may be necessary to encourage and facilitate research, development, and manufacture of countermeasure or to provide specifications for the countermeasure.” Additional language states a countermeasure is available for purchase under Project BioShield if it “is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years.” Eight years to licensure—that is the statutory standard established by Congress.

However, in all of its Bioshield RFPs to date, HHS has required that products be at the IND stage of development—a relatively advanced stage of development, particularly in the context of WMD medical countermeasures. While there may be valid reasons for HHS wanting to wait to obligate funds for products only after they have essentially been proven after years of early testing and millions of dollars in development costs, this approach is one of the main reasons why there are so few biotech companies now participating in this market space and why there are virtually no large pharmaceutical companies participating at all.

In some respects the department's position seems akin to the Pentagon asking that defense contractors build new ships, tanks and aircraft with only a vague assurance that there will actually be a buyer for them once they are developed and built. Moreover, HHS' apparent concern about spending federal funds on unproven drugs is inapplicable here. Companies that receive an advanced purchase contract under Bioshield only receive payment when the drug is approved and provided to the government. In any case, this approach is certainly no way to build a true biodefense industry in this country.

4. Building market confidence: In the last two-and-a-half years investors have lost confidence in the biodefense industry due to a number of factors. Initially, the long delay in the enactment of the Project Bioshield Act caused a loss of market confidence. Now it is the uncertain, mysterious, and bureaucratic process of securing an actual Bioshield contract that has caused companies, like mine, active in this area to take a beating in their share prices and in their ability to raise additional capital.

We believe this can and must be rectified by a more aggressive, predictable, and transparent Bioshield decision making process. As I mentioned earlier, I fully support efforts to enact a so-called Bioshield II bill, including key provisions to provided needed liability protection and additional financial incentives for companies to develop these countermeasures. However, I also firmly believe that much more can be done today, using existing federal authority and funding, to encourage private sector participation in this arena and to get a host of new countermeasures into the Strategic National Stockpile.

5. Communication: Mr. Chairman, if I had to pick one word to summarize how the Bioshield process must be improved, that word would be "communication." While I realize there are sometimes national security concerns that must be borne in mind when publicly discussing these issues, the fact of the matter is that it has been extraordinarily difficult, if not impossible, to find out anything about this process or about how we, as a small biotech company, might contribute to it. It truly has been a "black box" process, and one that we have had to hire several outside consultants to even begin to understand and participate in. HHS should now publicly indicate the threats for which it intends to buy products, along with reasonable information about the potential size of the order, the requirements for the products, and approximately when the order will occur. And then HHS should affirmatively open a dialogue with the pharmaceutical and biotechnology industries and with individual companies. Without better communication with industry, Project BioShield will very simply fail.

CONCLUSION

For Project Bioshield to be effective and stimulate private companies and investors to participate it simply needs to be implemented the way the law was written. I would encourage HHS, DHS, DoD and the other agencies and sub-agencies involved in this process to reach out even more to their partners in industry. For we are that: partners. We are not competitors with the federal government, nor are we seeking to simply profit from a new source of federal funds.

And I would venture to say that I and virtually all of my industry colleagues engaged in this market space are loyal, patriotic Americans who sincerely want to do our part to enhance our nation's security. We must certainly justify our efforts to do so to our shareholders, but I can assure you and the other members of this Committee that if profit were our only or even our primary motivation, we would have sought other markets or simply abandoned our efforts in this regard some time ago.

The efforts undertaken by this Committee, by Congress as a whole, and by this Administration to bring to fruition innovative new countermeasures are beginning to pay off. While much needs to be done to both clarify and streamline the decision making process, progress does appear to be being made.

Mr. Chairman, distinguished members of the Committee, we are truly on the dawn of a new era with respect to medical countermeasures to weapons of mass destruction. After decades of very little progress from the "duck and cover" days of the early Cold War, we are in the midst of extraordinarily exciting discoveries in vaccines and treatments for a host of man-made and naturally occurring pathogens, from anthrax and smallpox to botulinum and radiation.

The United States has the most innovative, persistent and effective pharmaceutical industry by far of any country in the world, and we have only begun to unleash that amazing potential for the protection of the American people from acts of terrorism. With the continued support and guidance of Congress, and with a Bioshield procurement process that is finally taken out of the shadows, the future could be very bright indeed.

Again, thank you for the opportunity to testify before your distinguished panel today, and I would be happy to answer any questions you may have.